

STATE MILK BOARD PROCEDURES REGARDING MANUFACTURING GRADE MILK

POLICY 1 – Somatic Cell Count

All manufacturing milk procurers are expected to conduct at least four official analyses for abnormal milk on each producer's deliveries each six months. For official regulatory purposes with individual producers, each plant is asked to designate those months of the year when official somatic cell counts will be conducted on all herds delivering milk. SMB MG 20 Official Months of Somatic Cell Count Determinations shall be used by each plant to notify the State Milk Board as to the months when "official" analyses of each producer's milk will be made. If more than one analysis is made during a month designated as official, the first analysis made during that month will be used.

Results of any additional analyses, beyond the designated four required, must be available for inspection and observation by representatives of the State Milk Board to determine correlation of results between additional analyses and the official analysis.

In designating official months when test will be made, consecutive months may not be skipped. For example, both June and July; or both May and June; or any other two consecutive months may not be omitted from testing.

The results of somatic cell counts from the first analysis conducted during months designated for "official tests" shall be reported on SMB MG 21 Notice of Probational or Undergrade Milk Quality and forwarded to the State Milk Board, PO Box 630, 1616 Missouri Boulevard., Jefferson City, MO 65102 within twenty-four hours or the next working day.

Whenever two of the last four analyses result in a high cell count, another analysis shall be made on the producer's milk after three days and before 21 days have elapsed. A report of the result of this test shall be forwarded to the State Milk Board within 25 days after the second high test occurred. If the results are 750,000 or less, only the date of test and actual count needs to be reported. If above 750,000 the date of test, actual count, and present schedule and frequency of milk pickup of this producer must be included along with the number of three-out-of-five violations for the producer during the previous twelve months. Use of SMB MG 21 Notice of Probational or Undergrade Milk Quality for reporting this information is required.

When this high cell count is reported, the State Milk Board, upon receipt of the report, shall notify the producer by mail on form SMB MG 16 Notice of Stop Sale of Producer Milk that following his next scheduled pickup of milk after the producer received the notice of "stop sale" by mail that he shall offer no milk for sale until authority for sale is reinstated. The pickup date on the stop sale will be 14 days from the date of the letter. If the producer receives a good count prior to that date, his permit may be reinstated. If the producer does not receive a good count by that date, he must then dump his milk until a

satisfactory sample is received by the State Milk Board office. This “stop sale” shall remain in effect until such time as the producer has:

1. made an examination of his herd and removed those cows showing udder inflammation;
2. serviced his milking equipment to assure that it is functioning properly with adequate vacuum and inflations are in good condition;
3. considered his milking routine to be sure it is not contributing to an elevated count,
4. thoroughly clean his facilities and reviewed his sanitary practices, and
5. a sample collected from the farm bulk tank and analyzed showing a somatic cell count 750,000 or less and reported to the State Milk Board office.

Following the completion of these five steps, the producer may request authority to sell manufacturing grade milk by contacting his approved fieldman and requesting a reinstatement inspection. The approved fieldman, upon receipt of the request, shall inspect the farm and complete a dairy farm inspection report. If it is his recommendation to reinstate authority to sell manufacturing grade milk, he shall mark the inspection report form in the “re-certified” block and forward the blue copy of the inspection report to the State Milk Board office. The producer may be authorized to commence the immediate sale of manufacturing grade milk if his approved fieldman has contacted the State Milk Board office by phone and advised that the producer has been re-certified and that the completed farm inspection report is in the mail to the Milk Board office. If this is the first violation of the three-out-of-five high somatic cell count for the producer within a twelve month period, the above inspection may be conducted with milk in the producer’s bulk tank or cans. If this is a second three-out-of-five violation for high somatic cell counts within a twelve month period, the producer’s bulk tank or can facility must be empty at the time of the inspection.

Following a “stop sale” for a high somatic cell count and after reinstatement, the regulatory agency may establish a new history. No analysis for somatic cell count shall be taken on the first pick-up following reinstatement, but on subsequent pick-ups, samples shall be taken at the rate of not more than two per week in a three-week period to provide an acceptable history of less than two high cell counts out of the last four analyses. This procedure is known as accelerated sampling and testing. Whenever less than two of the last four analyses are high, the producer shall be restored to the regular testing interval.

The State Milk Board office shall be notified no later than the next working day when a degraded Grade A producer desires to market manufacturing grade milk. Such a producer may obtain permission to immediately commence sale of his milk on the manufacturing grade market provided his approved fieldman has contacted the State Milk Board office by phone and the producer has complied with all other requirements as stated in this policy.

When permission is requested for a producer whose Grade A permit has been suspended because of high somatic cell count or elects degrade status while on a warning letter for two (2) out of four (4) high somatic cell tests, the manufacturing plant shall obtain a sample of his bulk tank milk and analyze it for somatic cell level and the result must be 750,000 or less. The accelerated sampling and testing routine must be applied to milk delivered from the degraded Grade A producer. Shall a favorable history of less than two (2) out of four (4) analyses fail to be established in 21 days following entrance to manufacturing market by this producer, a “stop sale” will be issued on his milk. When a “stop sale” must be applied, the producer must follow the procedure outlined herein for reinstating authority to ship manufacturing grade milk. There is a 14 day grace period for a degraded Grade A producer for any reason except well water. Fieldman will pick up a sample within the grace period.

If a Grade A milk producer’s permit has been suspended because of high bacterial estimate, he may sell and continue to sell his milk for manufacturing purposes provided he applies for authority to do so as outlined herein and that lab analyses of his first and subsequent shipments of milk comply with procedures and standards for manufacturing grade milk. If the suspension from Grade A was the result from antibiotic, pesticide, or water adulteration, a sample must be obtained, analyzed and proven to be negative before the milk can be picked up at the farm for manufacturing purposes.

SMB MG 26 – Rev. 01/10

POLICY 2 - Adulteration of Manufacturing Milk With Water

Official samples for added water are to be designated and taken twice each six months and unsatisfactory results reported to the State Milk Board office, 1616 MO Blvd, Jefferson City, MO 65102 on form SMB MG 21. Compliance is based on a freezing point of -0.525 degrees centigrade as a standard. The first unsatisfactory sample will require a warning letter. After five days from the date of the warning letter, a second official sample will be taken and analyzed. Unsatisfactory analysis on the second sample taken after five days will result in a “stop sale of manufacturing milk” being applied to the producer’s milk. The “stop sale” will remain in effect until the producer has contacted his approved fieldman to perform a reinstatement inspection on his farm and the inspection form SMB MG 23 is submitted to the State Milk Board office noting probable cause of water adulteration to be corrected and a satisfactory sample of milk has been obtained showing no adulteration may enter the manufacturing grade market only after a sample is obtained from his milk showing no adulteration with water. A degraded Grade A producer may remain on the manufacturing market as long as he complies with all requirements for manufacturing milk production.

SMB MG 27 – Rev. 2/87

POLICY 3 – Bacterial Estimate Classification Testing For Manufacturing Grade Milk

Official samples for bacterial estimate classification are to be conducted once a month on all producers of manufacturing grade milk and unsatisfactory results reported to the State Milk Board Office on form SMB MG 21 within 24 hours or the next working day when regulatory action is required. Compliance is based on direct microscopic clump count or standard plate count of not over 500,000 per ml. If more than one test is conducted on a producer's milk during the month then the first sample taken that month will be designated as the official sample for regulatory purposes. The first unsatisfactory sample will require a Notice of Probational or Undergrade Milk Quality form SMB MG 21 to be sent to the producer. The producer's milk must then be sampled for bacteria count at least once per month and the producer notified immediately of each count. Two (2) high of the last four (4) counts taken requires a warning to the producer that a sample will be collected following three (3) days and before 21 days. Unsatisfactory results from the accelerated sample will cause a "stop sale" to be issued on the producers milk. The "stop sale" will remain in effect until the producer has contacted his approved fieldman to perform a reinstatement inspection on his farm and an acceptable sample of milk taken showing acceptable bacteria limits.

SMB MG 31 – REV 04/02

POLICY 4 - Antibiotic, Radionuclide, and Pesticide Tests of Manufacturing Grade Milk

All manufacturing milk procurers are expected to conduct at least four official analyses for antibiotics on each producer's deliveries each six months. For official regulatory purposes with individual producers each plant is asked to designate those months of the year when official antibiotic tests will be conducted on all herds delivering milk. SMB MG 20 Official Months of Antibiotic testing shall be used by each plant to notify the State Milk Board as to the months when official tests of each producer's milk will be made. The official antibiotic tests may be made at the same times as the official somatic cell counts are taken for reporting purposes.

In designating official months when tests are to be made, consecutive months cannot be skipped.

An analysis showing antibiotics in manufacturing milk will cause a Stop Sale SMB MG 16 to be issued on that producer's milk. No milk may be picked up from the producer until he applies for a reinstatement inspection to his approved fieldman, the inspection is performed and the inspection form forwarded to the State Milk Board Office. A sample of the producer's milk taken and analyzed as no antibiotics shown before pickup by the farm bulk truck.

Upon receipt of the inspection form from the fieldman and negative test results from the lab on form SMB MG 21. The State Milk Board Office will issue Authority to Sell Manufacturing Grade Milk.

Pesticide testing on manufacturing grade milk will be performed when a reason presents itself to suspect a producer's milk of contamination. The State Milk Board Office is to be notified immediately of any situation concerning suspected pesticide contamination of milk. Milk suspected of pesticides shall not be offered for sale until showing tests to be free of pesticide residues. If the milk is confirmed to contain pesticides, it will be excluded from the market and a Stop Sale will be issued to the producer. After a Stop Sale is issued, a sample must be obtained showing no pesticide contamination of the producers milk and a farm inspection by his approved fieldman must be conducted and reported to the State Milk Board Office on form SMB MG 23 noting probable cause of contamination to be corrected before the producer is issued "Authority to Sell Manufacturing Grade Milk".

Radionuclide sampling and testing will be conducted according to federal requests and procedures. This will be accomplished as requirements arise and the State Milk Board Office is notified of these requirements.

SMB MG 35

POLICY 5 - Manufacturing Grade Milk and Milk Product Recall

This policy establishes the procedure to follow relating to a State Milk Board requested voluntary industry recall of adulterated or misbranded manufactured milk and milk products. This procedure may be used in lieu of embargo or impounding of such products and/or preferring charges against industry persons whose products are involved. Embargo of foods including dairy products is an authority of the Missouri Department of Health granted by section 196.570 RSMo (1978). That authority is further delineated in the Department's procedural manual Part IV Chapter IV, page 4. The impounding of manufactured dairy products and/or preferring charges is an authority of the State Milk Board or its authorized representatives under Section 196.570 RSMo. 1982 and the products are further identified in Section 196.545 RSMo. 1982.

In situations where manufactured dairy products in distribution are causing, appear to be causing, or pose an eminent threat of causing a hazard to the public health, an evaluation of the hazard will be conducted by an Ad Hoc committee of the Department of Health and the State Milk Board. (This Committee is the State Department of Health Deputy Director of Environmental Health/Epidemiology Services, the Director of the Bureau of Community Sanitation, The State Milk Board Executive Secretary, Program Coordinator and the Director of the Milk Board Contractee Local Health Department where the hazard originates.)

The Committee will take into account at least the following:

- (1) Whether any disease or injuries have already occurred from the use of the product.
- (2) Whether any existing conditions could expose or contribute to the exposure of humans to a health hazard. Any conclusion shall be supported completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
- (3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
- (4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
- (5) Assessment of the likelihood of occurrence of the hazard.
- (6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

On the basis of this determination, the Committee will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

Voluntary recalls are classified as follows:

- (1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- (2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- (3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Once a recall is initiated, its effectiveness until completed will be checked by the Department of Health-State Milk Board Ad Hoc Committee using the FDA guide entitled "Methods for Conducting Recall Effectiveness Checks". (See attached.)

The recalling industry is requested to submit periodic recall status reports to the State Dept. of Health and State Milk Board so that an assessment of the recall progress may be made. The frequency of such reports will be determined by the Ad Hoc Committee in each recall case; generally the reporting interval will be between 2 and 4 weeks.

Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

- (1) Number of consignees notified of the recall, and date and method of notification.

- (2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
- (3) Number of consignees that did not respond.
- (4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
- (5) Number and results of effectiveness checks that were made.
- (6) Estimated time frames for completion of the recall.
- (7) Recall status reports are to be discontinued when the recall is terminated by the committee.

A recall will be terminated when the Committee determines that all reasonable efforts have been made to remove or correct the products and when it is responsible to assume that the products subject to the recall have been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the Committee.

A recall can be disruptive of an industry's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. The following is provided as guidance for industries' consideration:

- (a) Prepare and maintain a current written contingency plan for use in initiating and affecting a recall.
- (b) Use sufficient coding of dairy products to make possible positive lot identification and to facilitate effective recall of all violative lots.
- (c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds that shelf life and expected use of the product.

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